

Applicants: Guy Benchley et al.
Application No.: 10/809,946

REMARKS

The Claim Amendments

Claim 13 has been amended such that a definition is provided for the variable "n." Support for this amendment is found in the claim as originally filed.

Claim 19 has been amended such that a definition is provided for the variable "n." Support for this amendment is found in the specification in paragraph [0054] on pages 18-19.

Claims 32 and 34 have been amended such that redundancies in the definitions have been deleted. Support for these amendments is in the claims as originally filed.

Claims 36 and 37 have been amended to delete the redundant recitation of the term " $(\text{CH}_2)_n\text{C}(\text{O})\text{R}^?$." Support for these amendments is found in the claims as originally filed.

Claim 43 has been canceled.

None of the amendments contain new matter. Their entry is requested.

Applicants reserve the right to pursue canceled subject matter in the instant application or in any application claiming priority therefrom.

The Response

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner states that he has considered the amendment filed on November 13, 2006, but has maintained the rejection of claim 43 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. In order to expedite prosecution, applicants have canceled this claim, thereby obviating the rejection.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 13, 19, 32, 34, 36, and 37 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner states that (i) the variable "n" is not defined in claims 13 and 19; (ii) claims 32 and 34 contain redundant

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definitions for the variables "m" and "n"; and (iii) the term " $(\text{CH}_2)_n\text{C}(\text{O})\text{R}^7$
 $(\text{CH}_2)_n\text{CH}_3$ " is not understood in claims 36 and 37. Claims 13, 19, 32, 34, 36, and 37
have been amended to correct the deficiencies pointed out by the Examiner, thereby
obviating the rejection.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 7-19, 31-40, 43-44, and 46-47 under 35
U.S.C. § 103(a), for allegedly being obvious over Cochran et al., International
Application Publication No. WO 02/096905, (hereafter "Cochran"). The Examiner
states that the unsubstituted 4-(thiazol-2-yl)pyrimidine compounds taught by Cochran
are structural homologs of the compounds of the invention where the thiazol-2-yl
group is substituted by a methyl group. Therefore, the Examiner asserts that it would
have been obvious to one skilled in the art at the time of the invention to prepare the
compounds of the present invention because such structurally homologous compounds
would be expected to possess similar properties. Further, the Examiner states that the
data used to support applicant's argument in November 13, 2006 Reply were not
properly submitted and must be presented in an appropriate declaration so that these
data can be properly understood by one skilled in the art. Applicants traverse in part.

Applicants submit concurrently herewith a Declaration under 37 C.F.R. §
1.132 by Francesco Salituro (hereinafter, "the Salituro declaration"), providing IC₅₀
data for the inhibition of mast cell degranulation by compounds of the invention and
compounds that are generically described by Cochran. These data allow for a head-to-
head comparison of compounds that contain an unsubstituted thiazole moiety (see
Cochran) and analogous compounds of the invention wherein the thiazole ring is
substituted with a methyl or hydroxymethyl group.

As seen in Exhibit A of the Salituro declaration, the novel substituted thiazole
analogs of the present invention are nonobvious over the unsubstituted thiazole
analogs of Cochran because they have improved pharmacological properties. For
instance, studies on the degranulation of mast cells demonstrate that compounds of

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formula I with substituents on the thiazole ring inhibit mast cell degranulation with a potency that is at least two times greater than corresponding compounds with an unsubstituted thiazole. See the IC₅₀ values in Exhibit A of Salituro declaration for Compound Nos. I-109, I-144, and I-145 of the present invention vs. the corresponding unsubstituted Compound A and Compound Nos. I-82, I-83, and I-84 of the present invention vs. the corresponding unsubstituted Compound B. Since Cochran does not teach or suggest compounds having a substituted thiazole ring and that these compounds would have improved pharmacological properties over unsubstituted thiazoles, the compounds of the present invention are not obvious. Therefore, applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claims 1, 7-19, 31-40, 43-44, and 46-47.

Rejection under obviousness-type double patenting

The Examiner has provisionally rejected claims 1, 7-19, 31-40, 43-44, and 46-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 17-30, 34, and 36-44 of copending U.S. Patent Application Serial No. 10/809,944 (hereinafter "the '944 application"). Applicants traverse.

Applicants do not acquiesce to the Examiner's assertion that the claims of the instant application are obvious over any of the co-pending claims of the '944 application. Furthermore, according to MPEP 804 (I)(B), a provisional double patenting rejection should continue to be made only for so long as there are conflicting claims in more than one application, unless that provisional double patenting rejection is the only rejection remaining in at least one of the applications. Accordingly, if no other substantive matters remain to be resolved in the instant application, applicants request that the provisional double patenting rejection be withdrawn.

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Conclusion

Applicants request that the Examiner enter the above amendments, consider the accompanying arguments, and allow the claims to pass to issue. Should the Examiner deem expedient a telephone discussion to further the prosecution of the above application, applicants request that the Examiner contact the undersigned at his convenience.

Respectfully submitted,



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